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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/308,195	05/12/1999	ERIC THIBAULT	410.016	5847

7590 11/06/2003

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EXAMINER	
RIMELL, SAMUEL G	
ART UNIT	**PAPER NUMBER**
2175	19

DATE MAILED: 11/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/308,195	THIBAULT ET AL.	
	Examiner	Art Unit	
	Sam Rimell	2175	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-8 and 10-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-8 and 10-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

SAM RIMELL
PRIMARY EXAMINER

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Preliminary Note: This office action includes new grounds of rejection which are not necessitated by the amendment of August 19, 2003. Accordingly, this office action is made non-final.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2-6, 8 and 10-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Killian (PCT Document WO 94/11838, published May 26, 1994).

Claims 15 and 16 are the independent claims of record, and thus will be addressed first.

Claim 15: FIG. 1 discloses several different entities, including an operational entity (data management system 12); preparation laboratory (processing center 16) and treatment laboratory (other processing centers 17 or incubation stations 20). The present invention pertains to the testing of blood which has been withdrawn from blood donors and which will be subsequently re-injected into other patients. The blood is treated in the sense that it is tested with reagents to determine if it cannot be re-injected into patients (page 15, line 17 through page 16, line 7).

FIG. 5 illustrates one of several different standard operating procedures that are performed in conjunction with the testing of the blood. FIG. 5 involves the validation of a lot of reagents used in the testing of the blood. As seen in FIG. 5, the user follows a series of sequential validation steps to validate a single lot of reagents used in the blood testing. The steps followed in FIG. 5 are sequential in the sense that they must be followed in an exact order. The steps are conditional in the sense that the subsequent steps are not reached until previous steps are

completed. For example, step 82 will not occur until step 80 is performed. Some of the steps are also conditional in the sense that they require "if-then" tests. Steps 74 and 84 are conditional steps which involve "if-then" decisions.

The data is processed and entered into a database (88). The data entered into the system is indicative of operators (see "Tech ID" at step 72) and the state of progress (whether the steps have been completed, such as by the production of a summary report). The summary report becomes the final certification.

Any of the information entered in FIG. 5 can be read as post-reinjection information, since the information may be entered at any time, such as after a previously approved lot of blood samples has been approved and the blood associated with those samples has been re-injected.

Claim 16: See remarks for claim 1.Note that the medical process of performing cytapheresis is not part of the physical system for processing information, and therefore is considered to not carry patentable weight.

Claim 2: The final certification is the issuance of the summary report (step 100). The summary is not generated until the password is entered (step 70).

Claim 3: Each of the steps of FIG. 5, except for steps 74 and 84, involve the entry of data into a screen page on a computer. That page is readable as the "screen page corresponding to a stage process number". Since all of the screen pages in FIG. 3 are optionally recited, the prior art need illustrate only one such page.

Claim 4: Step 72 of FIG. 5 calls for the entry of a technician ID, which means that the screen page is coded with the technician ID. The technician ID is also readable as an ID for the

patient, since no patentable distinction can be made by considering who the ID actually belongs to. As long as the prior art discloses the presence of such ID, who it belongs to does not create a patentable distinction (Non-functional descriptive material does not distinguish over the prior art in terms of patentability. See MPEP 2106, Section VI and *In re Gulack* 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983)).

Claim 5: The process of FIG. 5 is not exited until the printing of the screen page, as illustrated at step 100.

Claim 6: The preparation laboratory is readable the processing center (16) which receives the reagent kits which are tracked via the process of FIG. 5. The entity which provides the reagents is readable as an operational entity.

Claim 8: The preparation laboratory is readable as the processing center (16). The control laboratory is any entity which supplies the reagent kits to the processing center. Conditional steps such as 74 and 84 in FIG. 5 and testing step 78 in FIG. 5 are readable as control tests.

Claim 10: The preparation laboratory is readable as the processing center (16). Steps 66-100 as defined in FIG. 5 are readable as "n" number of management steps.

Claim 11: FIG. 1 defines a communication network. Each of the processing centers on the network are readable as a collection center since they collect blood samples and reagents so as to perform blood testing.

Claims 12-13: The purpose of the system of Killian is to perform tests on donated blood which is intended to be reinjected into patients. Since blood has both cells and genes, the reinjection of donated blood is both a cell therapy and a gene therapy. Thus, the system of

Killian defines quality management steps which are part of an overall cell therapy or gene therapy protocol.

Claim 14: Any usage of the computer system of Killian is readable as operator training.

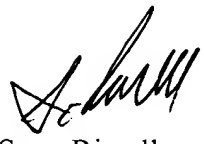
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Killian (WO 94/11838) in view of Official Notice.

Claim 7: Killian does not disclose its system as associating with a cytapheresis service (a service or method which separates red blood cells from plasma). However, Examiner takes Official Notice that such services are well known and typically performed in hospitals. Thus, if the system of Killian communicates with a hospital, it becomes associated with a cytapheresis service, since a hospital contains such a service on its premises. It would have been obvious to one of ordinary skill in the art to modify Killian to establish a line communication with a hospital so as to permit coordinated movement of blood donations from the hospital to the testing center of Killian. In such an arrangement, the testing center of Killian would be come associated with the hospital, which contains a cytapheresis center.

Any inquiry concerning this communication should be directed to Sam Rimell at telephone number (703) 306-5626.



Sam Rimell
Primary Examiner
Art Unit 2175